UNITED STATES PATENT AND TRADEMARK OFFICE

**Patent Maintenance Fees** 01/02/2002

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|---|---|---|---|---|---|---|---|
| **Patent Number** | 5464864 | **Issued** | 11/07/1995 | **Application Number** | 08167846 | **Filed** | 12/23/1993 |
| **Status** | 8th year fee window opens: 11/07/2002 | | | | | **Small Entity** | NO |
| **Window Opens** | 11/07/2002 | **Surchg Due** | | | | **Expiration** | |
| **Fee Amt Due** | 2020 | **Surchg Amt Due** | | | | **Total Amt Due** | 2020 |
| **Fee Code** | 184 | MAINTENANCE FEE DUE AT 7.5 YEARS | | | | | |
| **Surchg Code** | | | | | | | |
| **Title** | USE OF TETRAHYDROCARBAZONE DERIVATIVES AS 5HT1 RECEPTOR AGONISTS | | | | | | |

**Address for Fee Purpose**

MARY E. MCCARTHY
SMITHKLINE BEECHAM CORPORATION
CORPORATE PATENTS US., UW2220
P.O BOX 1539
KING OF PRUSSIA PA 194060939

**Most Recent Significant Events (up to 7)**

1999/05/03 Payment of Maintenance Fee, 4th Year, Large Entity.
1999/04/01 Payor Number Assigned.
End of Maintenance History

New Query Print

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-006

Elan Pharmaceuticals
Attention: Sydney A. Gilman, PhD
800 Gateway Boulevard
South San Francisco, CA 94080

Dear Dr. Gilman:

Please refer to your new drug application (NDA) dated January 29, 1999, received January 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Frova (frovatriptan) tablets.

We acknowledge receipt of your submissions dated May 7, 2001 (2), June 1, 2001, July 17, 2001, September 12, 2001, October 26, 2001, and November 7, 2001. Your submission of May 7, 2001 constituted a complete response to our April 28, 2000 action letter.

This new drug application provides for the use of Frova (frovatriptan) tablets for the acute treatment of migraine.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-006." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified. We remind you of your Phase 4

commitment specified in your submission dated September 12, 2001. This commitment is to revise the infrared (IR) identification method VML251AM89-01 to improve method specificity, and to submit the revised method, with supporting validation data, within three months of approval.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). With the approval of frovatriptan in adults, we can now reconsider issuing a request for pediatric studies. In order to do so, we recommend you submit a revised Proposed Pediatric Study Request (PPSR) for review. We are deferring submission of your pediatric studies until 3 years after approval.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,
*{See appended electronic signature page}*
Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure